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An Assessment of Motor Recovery Following Spinal Anaesthesia with Bupivacaine and Bupivacaine Fentanyl Combination: A Randomized Controlled Trial

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ABSTRACT

Background: Patient's ability to stand and fully mobile following spinal anaesthesia is an important key factor pointing towards the complete motor recovery. Bupivacaine is the most commonly used local anaesthetic in clinical practice; however, prolong motor weakness delays the discharge with usual dose. We have added fentanyl as adjuvant to local anaesthetic to decrease the usual dose and compared the both. We hypothesised that bupivacaine alone versus bupivacaine-fentanyl combination do not differ in block onset and motor recovery time. **Methods:** This randomised, double-blind study had Institutional Ethics Committee approval and registered in Clinical Trial Registry-India (CTRI/2018/02/011777). 50 Adult patients, ASA I-II, selected on the basis of "Continuous outcome superiority trial" scheduled for lower abdominal and perineal surgeries. Patients were randomly divided into two groups. Group B (n=25) received spinal anaesthesia with 0.5% bupivacaine and group BF (n=25) received a 0.5% bupivacaine and fentanyl combination. The primary outcome was the total time required for complete ambulation after the induction of the spinal Anaesthesia. Secondary objective was the time to assess other motor recovery process sequentially as return of muscle power, gait and coordination. **Results:** We found most of the patients not able to perform the motor functions like deep knee bend, heel-shin touch, identify joint position even after 2 hours (hrs) of spinal injection. Whereas after 4 hrs a significant number of patients (22/25 i.e. 88%) in group BF were able to identify joint position as compared to group B (12/25 i.e. 48%) (p=0.002). Mean time required for unassisted ambulation was 6.77±1.27 hrs in group B as compared to 4.49±0.98 hrs in group BF with p<0.001. **Conclusion:** Though the onset of motor blockade was comparable in both the groups, the return of motor functions and ability to ambulate was significantly earlier in patients receiving bupivacaine-fentanyl combination than the bupivacaine alone.

Keywords: Motor Recovery, Bupivacaine- Fentanyl, Spinal Anaesthesia.

INTRODUCTION

The concept of ''faster functional recovery'' the fast-tracking from surgery was pioneered by Professor Henrik Kehlet in Denmark in the early 1990s.[1] The "functional recovery" is one of the components of post anaesthesia health implying the home readiness or safe discharge following ambulatory surgery.

One of the anaesthesiologist's priorities following surgery is to provide early functional recovery from the effect of anaesthetics so that the patient may resume his/her daily activities with early discharge from hospital, faster return to work in order to reduce the economic burden.[2]

The ability of patient to resume normal motor activities after discharge i.e. the home readiness should be considered one of the principal endpoints after ambulatory surgery and anaesthesia.[3] The literature on functional recovery and postural functions after spinal anaesthesia is limited.[4]

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The bupivacaine is most commonly used local anesthetic for spinal anaesthesia. However, its effects usually last 4 hrs. depending upon the concentration and site of injection.[5] Owing to its long duration of action on motor functions, the patient cannot ambulate and this delays the discharge and prolongs the stay in post anaesthesia care unit (PACU) after surgery. Fentanyl is a short-acting, lipophilic, synthetic opioid, used commonly as an additive with local anesthetics to improve the quality of spinal anaesthesia. Addition of fentanyl to bupivacaine for intrathecal route has several advantages including a synergistic analgesic effect and improved quality of spinal anaesthesia without delaying recovery.[6]

Present study was conducted to compare effect of intrathecal injection of bupivacaine opposed to bupivacaine-fentanyl combination on motor recovery function. Time to unassisted ambulation succeeding spinal anaesthesia was taken as the primary end point of functional motor recovery. We hypothesised that bupivacaine alone versus bupivacaine-fentanyl combination do not differ in block onset and recovery time but the functional motor recovery is faster in combination group.

MATERIALS AND METHODS

Study design, setting & participants

This bedside motor function assessment study was designed as randomized controlled, double blinded, single-center clinical study, conducted as a part of the postgraduate program in the J.N. Medical College and Hospital, AMU, Aligarh, a tertiary care referral Centre, and was approved by the Board of studies Department of Anesthesiology (dated: 28.12.15) and Institutional Ethics Committee (IEC/FM/18.2. 2016). The study was performed between September 2015 to December 2017and registered in Clinical Trial Registry-India (CTRI/2018/02/011777).

Patients between 18-60 years, ASA (American Society of Anesthesia) physical status I-II, scheduled for elective or emergency surgery under spinal anaesthesia for lower abdominal, perineal and lower limb surgeries, of < 2 hours duration, were included in the study. Patients with history of allergy to the study medications, psychiatric illness, neurologic or vestibular disease, morbid obesity and patients with any contraindication to spinal anaesthesia were excluded from the study. The overview flowchart of the entire clinical trial is presented as per CONSORT 2010 guidelines in [Figure 1].

Randomization and Blinding

After written informed consent 50 patients were randomized into two groups of 25 patients each, Group B and Group BF, by allocation into one group or other on an alternate basis by an assistant independent from the study. To facilitate blinding, both groups and observers were blinded to the tested drug. One assistant, who, under all aseptic precaution, prepared and coded the drug syringes with time, date of preparation and the patient number and was aware of the actual composition, both 0.5% heavy bupivacaine 2.5 ml (12.5mg), and bupivacaine fentanyl combination0.5% bupivacaine heavy 2.0 ml (10.0 mg) plus fentanyl 0.5ml (25 µg). The other investigators, blinded of actual drug composition, administered the drugs intrathecally and recorded the data. An investigator that did not perform the spinal and therefore was blinded to the local anesthetic used, tested the level of analgesia, complete motor blockage and subsequent motor recovery.

Anesthetic Procedure

The night before surgery, all patients were given an oral ranitidine 150-mg fasted eight hours before surgery. On arrival to the operating room, an 18-G intravenous cannula was fixed and then 10 ml/kg lactated Ringer's solution was administered over 15 min. Standard monitoring was applied included ECG, pulse oximetry, and noninvasive blood pressure and baseline vitals were recorded. For induction of spinal anaesthesia patients were placed in the sitting position. After the aseptic preparations the L2–L3 or L3–L4 intervertebral space was identified and infiltrated with 2% lidocaine, and the subarachnoid was identified via the midline using a 25-gauge whitacre needle the study solution was injected by an anesthesiologist, who was not aware on its content. The patient was placed supine immediately after injection and further clinical assessment was done by blinded investigator.

Postoperatively the motor function was assessed using straight leg raise test in the supine position (positive is indicative of return sensation at L1/2),[7] deep knee bends (S1) - full knee flexion and extension in the supine position, heel-to-shin maneuvers (L3/4) - touching the shins with the opposing heels in supine position, Joint Position (L5) - movement of great toe on command and modified Bromage scores (0 - No motor block; 1 - Inability to raise extended leg, able to move knees and feet; 2 - Inability to raise extended leg and move knee; able to move feet; 3 - Complete block of motor limb).[8] All the tests were performed before anaesthesia (baseline) and 5 min, 60 min, 2, 4 and 24 hours after the spinal injection. However, after 4 hrs of spinal injection, if any residual effects remained, the assessment was continued every 2 hours.

Temporal Measurements: The time to onset of spinal anaesthesia, time for Romberg test to become negative (patients' ability to stand without swaying with eyes closed for full one minute) and patients' ability to walk steadily without assistance were recorded.

Statistical analysis:

A pilot study was done with ten patients in each group. The mean time to complete ambulation was found to be 6.7 and 4.9 hours in control and study group, respectively. The significance level was taken as 5%, and power was taken as 90%. A minimum required sample size per group was calculated to be 22 and the minimum total required sample size was calculated to be 44.[9] Thus, a total of 50 patients, 25 in each group were taken to avoid attritions, nonconsenting, or drop outs. Statistical analysis of data was done with the help of appropriate statistical tests using the freely available XL stat add-in in Microsoft Excel 2013 (Microsoft Corporation, Redmond, Washington (U.S.A). The results were presented in number, percentage, mean, and standard deviation as appropriate. A value of $P < 0.05$ was considered statistically significant.

RESULTS

All 50 patients completed the study have comparable demographics ($p > 0.05$) [Table 1], having normal baseline motor functions in the form of normal leg raising test, deep knee bend, shin to heel touch test and joint position test (in supine position). All the study subjects were ambulatory and demonstrated an ability to perform Romberg test in standing Position, before transfer to the OR. Following spinal

anaesthesia all the patients achieved satisfactory surgical anaesthesia to T11–T12 level, none required supplemental intraoperative analgesia within 5 minutes of intrathecal drug administration.

Mean Bromage Score was comparable in pre-anaesthesia period and at 5minutes post spinal blockade in both the groups. However, at 1, 2 & 4 hours after spinal injection, patients of BF group were found to have statistically significant lower mean Bromage Scores as compared to patients of group B ($p<0.05$). [Table 2]

Evaluation of motor power using Leg Raise and Deep Knee Bend test showed no significant difference in both the groups throughout the perioperative study period. Intergroup comparison after SA was found statistically non-significant ($p>0.05$) [Table 2].

Assessment for recovery of coordination function in both the groups revealed that even with return of clinically significant motor power most of the patients were not able to perform heel-shin touch and joint position identification test until 2 hours post spinal blockade. However, recovery of coordination was faster in group BF subsequently at 4 hours ($p< 0.05$) [Table 3].

The mean time ± SD required for assisted ambulation was 4.98 ± 1.35 hrs in group B as compared to 3.66 ± 0.99 hrs in group BF ($p < 0.001$). Mean time ± SD required for Romberg Test to become negative was 6.15 ± 1.31 hrs in group B as compared to 4.23 ± 0.96 hrs in BF group ($p < 0.001$). The mean total time ± SD required for complete unassisted ambulation was 6.77 ± 1.27 hrs in B group as compared to 4.49 ± 0.98 hrs in group BF ($p < 0.001$ [Table 4].

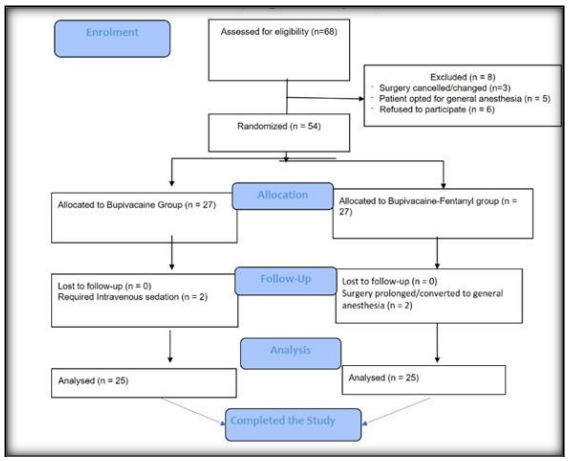

Figure 1: Flowchart of trial

Table 1: Demographic Data

Variables	Group B (n=25)	Group BF (n=25)	P value
Age in yrs.	40.80±13.01	34.44±11.27	0.108
Sex distribution (M/F)	10 (40%)/15 (60%)	16 (64%)/9 (36%)	0.27
Weight in kg	57.44±11.31	59.12±10.93	0.94
ASA grading (I &II)	7 (28.0%) & 18 (72.0%)	15 (60.0%) & 10 (40.0%)	0.13

Values are expressed as number or mean ±SD, ASA-American Society of Anesthesia physical status

Table 2: Return of motor power functions following spinal anaesthesia in supine position

Variables	Present/ Absent	Group B (n=25)	Group BF (n=25)	P value
Bromage Score (mean±SD)				
Pre-anaesthesia	Present	0.00	0.00	1.000
5 min after SA	Present	2.92±0.27	2.88±0.32	0.635
60 min after SA	Present	3.00±0.00	2.84±0.36	0.031*
2 hrs after SA	Present	2.69±0.47	2.50±0.76	0.002*
4 hrs after SA	Present	0.42±0.57	0.15±0.36	0.050*
6 hrs after SA	Present	0.00±0.00	0.00±0.00	1.000
Leg Raise Test				
Pre-anaesthesia	Present	25 (100%)	25 (100%)	1.000
5 min after SA	Absent	25 (100%)	25 (100%)	1.000
60 min after SA	Present	0 (0%)	0 (0%)	1.000
2 hrs after SA	Present	0 (0%)	1 (4%)	0.639
4 hrs after SA	Present	15 (60%)	21 (84%)	0.010*
6hrs after SA	Present	24 (96%)	25 (100%)	1.000
8 hrs after SA	Present	25 (100%)	25 (100%)	1.000
Deep Knee Bend Test				
Pre-anaesthesia	Present	25 (100%)	25(100%)	1.000
5 min after SA	Absent	25 (100%)	25 (100%)	1.000
60 min after SA	Absent	25 (100%)	25 (100%)	1.000
2 hrs after SA	Present	2 (8%)	3 (12%)	0.286
4 hrs after SA	Present	22 (88%)	24 (96%)	0.033*
6 hrs after SA	Present	25 (100%)	25 (100%)	1.000
8 hrs after SA	Present	25 (100%)	25 (100%)	1.000

Table 3: Return of Motor Co-ordination Functions following SA in Supine Position

Variables	Present/Absent	Group B (n=25)	Group BF (n=25)	P value
Heel-Shin Touch (L3/4)				
Pre-anaesthesia	Present	25 (100%)	25 (100%)	1.000

5 min after SA	Absent	25 (100%)	24 (96%)	0.344
60 min after SA	Absent	25 (100%)	25 (100%)	1.000
2 hrs after SA	Present	1 (4%)	2 (8%)	0.529
4 hrs after SA	Present	7 (28%)	14 (56%)	0.016*
6 hrs after SA	Present	25 (100%)	25 (100%)	1.000
Joint Position (L5)				
Pre-anaesthesia	Present	25 (100%)	25 (100%)	1.000
5 min after SA	Absent	16 (64%)	20 (80%)	0.040*
60 min after SA	Absent	25 (100%)	24 (96%)	0.387
2 hrs after SA	Present	3 (12%)	6 (24%)	0.378
4 hrs after SA	Present	12 (48%)	22 (88%)	0.002*
6 hrs after SA	Present	25 (100%)	25 (100%)	1.000

*significant difference

Table 4: Assessment of Gait

Variables	Group B (mean±SD)	Group BF (mean±SD)	P value
Time Required for Assisted Ambulation (Hrs)	4.98±1.35	3.66±0.99	<0.001*
Time Required for Negative Romberg Test (Hrs)	6.15±1.31	4.23±0.96	<0.001*
Time Required for Complete Ambulation (Hrs)	6.77±1.27	4.49±0.98	<0.001*

*significant difference, Hrs= Hours

DISCUSSION

Spinal anaesthesia is a commonly used technique for lower abdominal, pelvic, perineal and lower limb surgeries done on ambulatory basis, as it provides faster and effective onset of sensory and motor block, adequate muscle relaxation and prolonged postoperative analgesia.[10] The major reasons for prolongation in patient discharge are the delayed return of bladder sensory and motor function, along with the late return of dorsal column neural function for the lower limbs.[11]

Thus, the fast recovery after spinal anaesthesia is required to facilitate early ambulation after surgery, as the crucial component of early patient discharge is the ability to walk steadily without assistance. The ambulatory setting also dictates that the anesthetic techniques offered to patients need to provide rapid recovery, allowing discharge on the same day without compromising the safety and quality of care.[12] Positive performances on tests, such as the straight leg increase and deep knee bend, have been considered a marker of ambulatory capacity and were used to suggest that patients could walk unassisted from the operating room following spinal anaesthesia.[13] The outpatient ambulatory readiness has been assumed only, when clinical indicators such as return of adequate motor function are present or in reality negative Romberg test results.

Hence, the main challenge now is to prevent the prolonged motor block or impairment of joint position sense from delaying discharge.[14] To judge the ambulatory readiness, Imarengiaye et al.,[4] injected a mixture of 5 mg 0.5% heavy bupivacaine and 10 mic fentanyl and observed that majority of patients maintained motor function and proprioception sensation at the onset of surgical anaesthesia, were able to perform the straight leg raise, full knee flexion and extension and perform heel-to-shin maneuvers, and identify joint position in the supine position. Postoperatively, at 60 min after onset of spinal anaesthesia, 100% of the patients had recovered sensory and gross motor functions, but only 36% could stand, and 8% could walk without assistance, and it took 150–180 min for adequate ambulation. A study by Srivastava et al has shown that the addition of fentanyl to spinal lidocaine speeded the onset time for sensory block, improved the intraoperative analgesia, and delayed the time of demand for analgesia without affecting motor blockade or time to pass urine.[15]

Contrary to this, our study showed that the motor functions in supine position including straight leg rising, deep knee bend, heel-to-shin manoeuvres, and joint position (movement of great toe on command) was abolished within 5 minutes of injection in all the patients of both the study groups.

The notable difference was demonstrated in the recovery of motor functions, in terms of time taken to perform straight leg raise, deep knee bend, heel-to-shin manoeuvres, and joint position in supine position. The patients in group B took 6 hrs (approximately) to perform these manoeuvres, whereas the group BF took only 4 hours (approximately) to perform the same functions.

All patients in our study were able to do assisted ambulation in just 3.66±0.99 hrs (BF group) vs 4.98±1.35hrs (B group). The time required for Negative Romberg test was 4.23±0.96 hrs (BF group) vs. 6.15±1.31hrs (B group) hrs and ability to perform complete ambulation in 4.49±0.98 hrs (BF group) vs 6.77±1.27 hrs (B group).

The shortened recovery time, in the BF group as compared to group B, was seems to be due to lower dose of bupivacaine used in group BF.

Another study has also reported enhanced motor recovery and early ambulation when low dose bupivacaine & fentanyl combination was used in anorectal surgery.[16]

Thus, group BF achieved the home readiness earlier as compared to the group B.

Our study had limitations, the sample size was rather small, and a larger study is required to validate the present observations, the motor function recovery was not assessed at zero score of the modified Bromage scale, and therefore, further study is warranted with extrapolation of observations till zero

score of the modified Bromage scale to authenticate our findings and positive correlations.

CONCLUSION

The onset of motor blockade was fast in both the groups, the return of motor power, gait and coordination function was achieved significantly earlier in patients receiving bupivacaine-fentanyl combination. Thus, the addition of fentanyl to heavy bupivacaine for spinal anaesthesia provides earlier ambulation following surgery, than bupivacaine. Further studies needed for validation of our results.

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